

Application No. 09/369,231

## REMARKS

### I. APPLICANT'S INVENTION

Applicant's invention is a material having an improved modified surface of expanded polytetrafluoroethylene (PTFE) having a node and fibril structure. An expanded PTFE surface, treated according to the applicant's invention, has a high degree of surface roughness yet maintains a high degree of porosity. The enhanced roughness, combined with the high porosity, is believed to promote tissue attachment to the treated surface after implantation. Enhanced roughness of the surface is achieved by selectively creating a surface that includes both (1) ridges comprising clustered nodes interconnected by fibrils, and (2) multiple gnarled nodes protruding unsupported by fibrils from a valley floor. It is the combination of these two distinct surface properties that provides the highly unique structure of the material of the present invention.

### II. REJECTION OF CLAIMS

In the Office Action of April 4, 2001, claims 1-7 and 9 have been rejected under 35 U.S.C. §103(a) as being unpatentable over United States Patent 5,462,781 to Zukowski (hereafter "Zukowski patent") in view of United States Patent 4,713,070 to Mano (hereafter "Mano patent"). Additionally, claims 10 and 11 have been rejected under 35 U.S.C. §102(b) as being anticipated by Mano. As is explained below, with the above amendments both of these rejections have been fully overcome.

In applying the Zukowski patent the Office asserts:

"Zukowski teaches an expanded PTFE material having a microstructure of nodes interconnected by fibrils. The modification process taught by Zukowski creates a surface comprised of freestanding node portions having open valleys disposed between them."

Office Action of April 11, 2001, at 3-4. However, it is acknowledged that the Zukowski patent does not teach a surface that also includes a series of node clusters interconnected by fibrils ("Zukowski does not specially disclose the surface having a number of node clusters." Office Action of April 11, 2001, at 4).

In order to find this critical second portion of the present invention, the Office applies the Mano patent in the following manner:

"However, Mano discloses in analogous art that a PTFE material having a microstructure of nodes interconnected by fibrils, ridges, and valleys. The ridges are comprised of clustered nodes."

Application No. 09/369,231

Office Action of April 11, 2001, at 4. The Office then concludes that "[t]herefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the ridges of clustered nodes in the PTFE surface of Zukowski, motivated by the desire to obtain a porous structure of PTFE having improved strength." Id. This proposed combination of references simply does not withstand scrutiny.

The Zukowski patent teaches a surface modification process that removes fibrils from a surface of ePTFE material using a radio frequency gas plasma discharge with a reactive etching gas. Specifically, the Zukowski patent teaches that the expanded PTFE surface is "...modified by the removal of fibrils from the surface so that under magnification the surface has the appearance of freestanding nodes portions not interconnected by fibrils but having open valleys disposed between the freestanding node portions." Zukowski patent, Abstract, at lines 3-8. This produces a surface structure such as that shown in Figure 2A of the Zukowski patent. However, as is acknowledged in the current Office Action, the Zukowski patent does not teach combining freestanding nodes on a surface with node / fibril clusters on the same surface. Moreover, the Zukowski patent only discloses straight freestanding nodes (as shown in, for example, Figures 2A, 9A, and 13), with no teaching or suggestion as to how to modify such freestanding nodes to take on a "gnarled" configuration as shown, described, and claimed in the present application (see, e.g., Application Figures 4D, 4E, 5, 6A, 6D, 9C, and 9D; specification at page 9, line 14, through page 11, line 2).

The Office attempts to overcome the acknowledged deficiencies in the Zukowski patent by combining teachings with the Mano patent. The Mano patent teaches modifying a porous PTFE structure to provide a "...microfibrous structure composed of fibers and nodes connected to one another by these fibers..." wherein the microfibrous structure includes "... a portion having a strong orientation in one direction and a portion having a strong orientation in a direction at right angles to the aforesaid direction, the orientation of said microfibrous structure progressively changing from one said portion to the other." Mano patent, at Col. 1, lines 60-66. This oriented fiber and nodes structure is achieved using particular stretching and heating processes. See Col. 1, line 67, through Col. 2, line 11. Nothing in the Mano patent in any way suggests or teaches that freestanding nodes can be provided on its surface using its disclosed processes, much less that such freestanding nodes might be somehow beneficial. Finally, again, the patent is devoid of any suggestion of "gnarled" nodes in any form.

Contrary to the suggestion of the Office, even with the benefit of improper hindsight reconstruction, the teachings of the Zukowski and Mano patents cannot be combined to achieve

Application No. 09/369,231

the present invention as claimed. Claim 1 (amended) of the present application defines a material that comprises:

- a surface comprising PTFE having a node and fibril microstructure;
- the surface having a number of node clusters, said node clusters comprising multiple nodes interconnected by fibrils, and gnarled nodes situated between the node clusters; and
- said gnarled nodes having a protruding length and being substantially devoid of fibrils along the protruding length.

As has been explained, the Zukowski patent teaches only how to achieve straight, freestanding nodes on its surface, but it does not teach or suggest providing "node clusters" or "gnarled nodes" on its modified surface. The Mano patent teaches modifying fibril lengths in the node and fibril structure on its surface, but it does not teach how to provide nodes "devoid of fibrils" or how to form such nodes in a "gnarled" configuration. Finally, neither of these references provides any suggestion that it might be beneficial to provide a structure with all of the surface properties defined on claim 1 (amended).

Moreover, even if there were some suggestion to combine the processes of the Zukowski and Mano patents, the processes of these two patents are simply not combinable to achieve the present invention as claimed. If the process of the Zukowski patent were applied to the surface structure of the Mano patent, it would remove the surface fibrils from the oriented node and fibril surface and thus fundamentally alter the physical aspects of the surface. In other words, the process of the Zukowski patent would remove the interconnecting fibrils of the Mano surface, thus destroying any nodal clustered properties that might be present on the untreated final Mano surface. On the other hand, applying the two processes in the reverse order would again remove the fibrils and thus not produce any semblance of the node clusters of the present invention. In either instance, there is no reason to believe that gnarled nodes will be provided through any combination of these two processes. Accordingly, neither the Zukowski nor Mano patent teaches or suggests how to combine their processes to produce the present invention as now claimed in claim 1 (amended) or claim 2 (amended).

Further removed from either of these cited references is claim 10 (amended) that defines a material that comprises

- at least one node having a protruding length measured from a valley surface, the at least one node being substantially devoid of fibrils along its protruding length;
- the at least one node being adjacent to a ridge having a height; and
- the protruding length of the node being greater than the height of the adjacent ridge.

A

Application No. 09/369,231

This claim defines a particularly surprising aspect of the present invention – that its freestanding nodes can actually be longer than the adjacent surface structure from which the nodes were formed. As is explained in the present application, it is believed that this occurs as an artifact of the laser surface treatment process whereby the node is stretched in length prior to breaking free from adjacent structure. See Application, at page 10, lines 7-15. Nothing in either of the cited references in any way suggests that freestanding nodes can be created that are longer than the height of material from which they are formed, much less suggesting a process of how to create such nodes. This unique property is also claimed in dependent claims 3 (amended) and 12.

Accordingly, each of the independent claims 1 (amended), 2 (amended), and 10 (amended) patentably defines over all of the cited references and are in form for allowance. Additionally, the remaining claims, while being allowable as dependent on allowable subject matter, define aspects of the present invention that further patentably distinguish over the cited references. As such, all the claims now define subject matter that is both new and non-obvious over all of the cited references.

### III. FORMAL AMENDMENTS

A number of formal objections have been raised in the current Office Action. These are all addressed in the above amendments.

Applicant's representative had provisionally elected to pursue prosecution of Group I per the restriction requirement raised on March 30, 2001. Applicant hereby affirms this election and withdraws claims 8 without prejudice to re-filing as a divisional application at a later time.

Claims 1-7, 9-11 have been objected to under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. Specifically, the term "a surface," as recited in claim 1, and the term "a textured pattern," as recited in claim 2, are the basis for the claim rejection. Claims 1 and 2 have been amended to better define these elements of the claims. As amended, each of these claims now particularly points out and distinctly claims the distinct textured pattern of the present invention. Accordingly, the objection under 35 U.S.C. §112, second paragraph, has been fully addressed.

Claim 9 has been objected to because of its dependency to the non-elected claim 8. Applicant has withdrawn claim 9 without prejudice.

Finally, attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

Application No. 09/369,231

#### IV. CONCLUSION

For the foregoing reasons, each of the claims of the present application is now in form for allowance. Applicant respectfully requests reconsideration and allowance of claims 1 (amended), 2 (amended), 3 (amended), 4 (amended), 5-7, 10 (amended), and 12 -27. If any questions remain, applicant requests an interview prior to the next Office Action.

Respectfully submitted,



David J. Johns  
Reg. No. 31,527  
W. L. Gore and Associates, Inc.  
551 Paper Mill Road,  
P.O. Box 9206  
Newark, DE 19714-9206  
(928) 864-4800

Date: October 11, 2001

Application No. 09/369,231

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

Claim 1 has been amended as follows:

1. (amended) A material comprising:
  - a surface comprising PTFE having a node and fibril microstructure;
  - the [a] surface having a number of node clusters, said node clusters comprising multiple nodes interconnected by fibrils, and gnarled nodes situated between the node clusters; and
  - said gnarled nodes having a protruding length and being substantially devoid of fibrils along the protruding length.

Claim 2 has been amended as follows:

2. (amended) A material comprising:
  - a surface comprising PTFE having a node and fibril microstructure;
  - said surface comprising a textured pattern having multiple ridges and valley surfaces, [;] the ridges comprised of node clusters; [and]
  - said node clusters comprising multiple nodes interconnected by fibrils;
  - the valley surfaces having gnarled nodes protruding therefrom; and
  - said gnarled nodes having a protruding length and being substantially devoid of fibrils along the protruding length.

Claim 3 has been amended as follows:

3. (amended) A material according to claim 2 wherein
  - at least one gnarled node has a protruding length measured from a valley surface;
  - the gnarled node is adjacent to a ridge having a height; and
  - the gnarled node protruding length is greater than the height of the adjacent ridge[;and
  - the gnarled node is substantially devoid of fibrils along the protruding length].

Claim 4 has been amended as follows:

Application No. 09/369,231

4. (amended) A material according to claim 2 wherein  
a gnarled node has a longitudinal axis and a protruding length measured from the valley surface; and  
the longitudinal axis has at least two angular deflection points; and  
the gnarled node is substantially devoid of fibrils along the protruding length].

Claim 10 has been amended as follows:

10. (amended) A material comprising:  
at least one node having a protruding length measured from a valley surface, the at least one node being substantially devoid of fibrils along its protruding length;  
the at least one node being adjacent to a ridge having a height; and  
the [node] protruding length of the node being greater than the height of the adjacent ridge.

Claims 12 through 27 have been added as follows:

12. A material according to claim 1 wherein  
at least one gnarled node has a protruding length measured from a valley surface;  
the gnarled node is adjacent to a ridge having a height; and  
the gnarled node protruding length is greater than the height of the adjacent ridge.
13. A material according to claim 1 wherein  
the gnarled node has a longitudinal axis and a protruding length measured from the valley surface; and  
the longitudinal axis has at least two angular deflection points.
14. A material according to claim 1 wherein  
said surface comprises a textured pattern having multiple ridges; and  
the multiple ridges are substantially parallel to each other.
15. A material according to claim 1 wherein  
the material is a sheet having two opposing surfaces; and  
one opposing surface has multiple ridges and valleys.

Application No. 09/369,231

16. A material according to claim 1 wherein  
the material is a sheet having two opposing surfaces; and  
the two opposing surfaces have multiple ridges and valleys.
17. A material according to claim 1 wherein the material comprises an implantable medical device.
18. A material according to claim 17 wherein the material comprises an implantable sheet.
19. A material according to claim 2 wherein the material comprises an implantable medical device.
20. A material according to claim 19 wherein the material comprises an implantable sheet.
21. A material according to claim 10 wherein  
the surface comprises a PTFE having a node and fibril microstructure; and  
the surface has a number of node clusters, said node clusters comprising multiple nodes interconnected by fibrils, and the at least one node having a protruding length is situated between the node clusters.
22. A material according to claim 10 wherein  
the at least one node having a protruding length node has a longitudinal axis; and  
the longitudinal axis has at least two angular deflection points.
23. A material according to claim 10 wherein  
the material includes a surface having a textured pattern having multiple ridges; and  
the multiple ridges are substantially parallel to each other.
24. A material according to claim 10 wherein  
the material is a sheet having two opposing surfaces; and  
one opposing surface has multiple ridges and valleys.
25. A material according to claim 10 wherein  
the material is a sheet having two opposing surfaces; and  
the two opposing surfaces have multiple ridges and valleys.
26. A material according to claim 10 wherein the material comprises an implantable medical device.
27. A material according to claim 26 wherein the material comprises an implantable sheet.

Claims 8, 9, and 11 have been cancelled.